State of Washington Notice of Sole Source Award N22399

Fred Hutchinson Cancer Research Center

The Washington State Department of Health (DOH) is awarding a sole source contract to Fred Hutchinson Cancer Research Center to conduct case finding, data collection, quality assurance and educational activities in the thirteen counties of the National Cancer Institute's Surveillance, Epidemiology and End Result (SEER) program and transmit that information to the Washington State Cancer Registry.

The Fred Hutchinson Cancer Research Center, Cancer Surveillance System (FHCRC/CSS) has a well-established cancer data collection and quality assurance program in the thirteen county region of Puget Sound (Whatcom, Skagit, Snohomish, King, Pierce, Thurston, Grays Harbor, Mason, Kitsap, Jefferson, Clallam, San Juan and Island counties). Since 1974 the CSS has conducted its activities under contract with the U.S. National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program. To qualify as a NCI/SEER contractor, the contractor must operate in a state with a mandatory cancer reporting law like RCW 70.54.230 - .270.

Hospitals, treatment centers, physician offices, medical clinics and pathology laboratories, in the above described region, are currently under agreement with FHCRC/CSS to allow access to medical records and/or report new incidence cases for the purpose of cancer reporting. FHCRC/CSS is staffed by cancer data collection personnel who have expertise in cancer case reporting quality assurance review, and meet certification requirements.

RCW 70.54.230 authorizes DOH to enter into a contract with a cancer research institution to support the efforts of the WSCR. The proposed contractor is long established in the Puget Sound area and is believed to be the only source available in the geographic area capable of performing the services required under this contract.

The contract will be issued on or about October 3, 2016 for approximately 60 months. The dollar value is estimated at approximately \$95,000/year.

This is not an invitation to bid. However, vendors contemplating the above requirements may submit capability statements detailing their ability to meet the state's requirements within five (5) calendar days of this announcement. In the absence of other qualified sources, it is the state's intent to make a sole source award of the contract.

Send inquiries or capability statements to:

Brad Halstead
Department of Health Contracts Unit
Email: <u>Brad.Halstead@doh.wa.gov</u>
(360) 236-3904

THIS AGREEMENT is made by and between the Washington State Department of Health (DOH) and the following:

CONTRACTOR NAME and ADDRESS:

Fred Hutchinson Cancer Research Center (FHCRC), Cancer Surveillance System 1100 Fairview Ave. N, MS JB-500 PO Box 19024 Seattle WA 98109-1024

UBI#: 600-143-789

BACKGROUND

DOH and FHCRC wish to enter into an agreement under which FHCRC will collect for DOH certain data concerning the incidence of cancer. The Parties additionally wish the agreement to specify the rights and responsibilities of the parties in connection with the data. This agreement is affected by the following considerations:

- Under the Revised Code of Washington (RCW) 70.54.230 -.270, Washington State established the Washington State Cancer Registry (WSCR) to monitor the incidence of cancer within the State of Washington and provide high-quality data for statistical reporting, research and public health purposes.
- RCW 70.54.240 requires certain health care facilities and providers to report certain cancer information to WSCR. DOH's rules for cancer reporting are codified at Chapter 246-102 Washington Administrative Code (WAC).
- RCW 70.54.230 authorizes DOH to enter into a contract with a cancer research institution to support the
 efforts of the WSCR.
- Fred Hutchinson Cancer Research Center (FHCRC) separately and independently operates the Cancer Surveillance System (CSS), a population based cancer registry. CSS was established in 1974 with the mission of 1) collecting data on incident cancer cases among residents of thirteen counties in western Washington, including Clallam, Grays Harbor, Island, Jefferson, King, Kitsap, Mason, Pierce, San Juan, Skagit, Snohomish, Thurston, and Whatcom Counties (CSS Area) and 2) making the collected data available for research that addresses the causes and consequences of cancer. Since 1974, the CSS has conducted its activities under contract with the U.S. National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program. To qualify as a NCI/SEER contractor, the contractor must operate in a state with a mandatory cancer reporting law like RCW 70.54.230 -.270.
- DOH has contracted with FHCRC since 1993 for work authorized under RCW 70.54.230. As an independent contractor, CSS has collected data from reporters in the CSS Area.
- Funds received from DOH are in addition to the NCI/SEER funding received by FHCRC. The Statement of Work (SOW) attached to this Contract describes activities that the FHCRC performs with funding provided by DOH.
- FHCRC uses the data collected to conduct research projects internally and responds to research requests from external research entities. Depending on the research, the data used may identify individuals or it may be data from which individually identifiable information of individuals and their relatives and household members has been removed (de-identified data).
- Under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and RCW Chapter 70.02, Washington's Medical Records Act, the health care facilities and providers must not disclose certain

- health care information without the patient's authorization, except where the law otherwise permits or requires disclosure. There is such an exception for information collected for WSCR under 45 Code of Federal Regulations (CFR) § 164.512(b) (1) (i) and RCW 70.02.050(2), which authorize reporting to governmental entities for public health purposes.
- Under RCW 42.48.020(2), DOH may release an individually identifiable patient record in its possession for research purposes without the informed consent of the patient only in certain circumstances: a human research review board (also known as an "Institutional Review Board" or "IRB") must approve the disclosure; the disclosure must not violate federal law; and the researcher must enter into a confidentiality agreement with certain provisions before disclosure. Under WAC 246-102-020, DOH may release the data collected under this Contract to a researcher after the research project has been reviewed and approved by the Washington State Institutional Review Board (WSIRB) and the researcher has entered into a confidentiality agreement conforming to both RCW 42.48.020 and the DOH's data security requirements. Under 45 CFR § 164.512(i), an entity covered by HIPAA, may disclose protected health care information if an Institutional Review Board (IRB) has approved the disclosure and the covered entity obtains certain assurances from the researcher.
- Some information collected and maintained by FHCRC for WSCR may be Public Records as defined by Chapter 42.56 RCW, the Public Records Act. Certain portions of such records may be exempt from disclosure.

THEREFORE, the Parties agree as follows:

TERMS AND CONDITIONS

- 1. STATEMENT OF WORK (SOW): FHCRC shall provide all necessary personnel, equipment, materials, goods, and services and otherwise do all things necessary for or incidental to the performance of the work described in Exhibit A, which is incorporated into this Agreement.
- 2. **PERIOD OF PERFORMANCE:** The initial period of performance is from the **Date of Execution** through **September 30, 2017** unless terminated earlier as provided by this Agreement. Depending on the availability of funding, this contract may be extended via amendment until **September 30, 2022**. No billable activity may take place until this Agreement has been signed by both Parties.
- **3. CONSIDERATION:** The maximum amount available under this Agreement shall not exceed Ninety-five Thousand and 00/100ths Dollars (\$95,000.00).

4. INVOICES AND PAYMENT:

- 4.1. FHCRC shall submit invoices to the DOH Project Manager for all amounts to be paid. Invoices must reference this contract number and provide detailed information as requested. All invoices must meet with DOH approval prior to payment; approval will not be unreasonably withheld. DOH will authorize payment only upon satisfactory completion and acceptance of deliverables and for allowable costs as outlined in the statement of work and/or budget. DOH will return all incorrect or incomplete invoices and will not pay for services that occur outside the period of performance. FHCRC will not invoice DOH for services paid for by NCI/SEER.
- 4.2. DOH will issue payment within 30 days of receiving a correct and complete invoice and approving the deliverable(s). DOH must receive correct and complete invoices within 60 days of the Agreement expiration date. Payment of claims submitted more than 60 days after the expiration date is subject to DOH's discretion and contingent upon the availability of funds.
 - 5. CONTRACT MANAGEMENT The individuals listed below or their successor shall be the main points of contact for services provided under this Agreement. DOH's Project Manager or successor is responsible for monitoring FHCRC's performance and the contact person for all communications regarding contract performance, deliverables, and invoices. The Project Manager has the authority to accept or reject the services provided and if satisfactory, certify acceptance on each invoice submitted for

payment. Notifications regarding changes to this section must be in writing (e-mail acceptable) and maintained in project file but will not require formal contract amendment.

FHCRC Project Manager	DOH Project Manager
Stephen M. Schwartz PO Box 19024	Patti Migliore Santiago PO Box 47855
MS M4-C308	Olympia WA 98504-7855
Seattle WA 98109-1024 Phone : (206) 667-4460	Phone: (360) 236-3645 Fax: (360) 664-2619
Fax: (206) 667-5948	Email: patti.miglioresantiago@doh.wa.gov
Email address: sschwart@fhcrc.org	

- **ORDER OF PRECEDENCE** The items listed below are incorporated in this Agreement. Any conflict or inconsistency in this Agreement shall be resolved by giving the documents precedence in the following order:
 - Applicable Federal and State Statutes and Regulations
 - Terms and Conditions
 - Exhibit A
 - Any other document expressly incorporated by the Terms and Conditions
- **7. ENTIRE AGREEMENT** This Agreement, including incorporated items, constitutes the entire agreement between the parties and supersedes all prior oral or written agreements, commitments, or understandings concerning the matters provided for in this Agreement.
- **8. ACCESS TO BUSINESS RECORDS -** FHCRC shall provide reasonable access to its business records connected to this Agreement to DOH, the Joint Legislative Audit and Review Committee, and the State Auditor at no additional cost. This includes access to all business records that support the reports generated by FHCRC as described in the SOW.
- **9. ADVANCE PAYMENTS PROHIBITED** DOH will make no payment in advance or in anticipation of services or supplies.
- **10. AMENDMENTS** the parties may amend this Agreement by mutual written agreement. Amendments are not binding unless in writing and signed by personnel authorized to bind each of the parties. FHCRC assumes sole risk for work performed before an amendment is signed by both parties.
- 11. AMERICANS WITH DISABILITIES ACT (ADA) OF 1990, PUBLIC LAW 101-336, also referred to as the "ADA" 28 CFR Part 35 FHCRC must comply with the ADA, which provides comprehensive civil rights protection to individuals with disabilities in the areas of employment, public accommodations, state and local government services, and telecommunication
- **ASSIGNABILITY** FHCRC shall not transfer or assign this Agreement or any claim arising under this Agreement without prior written consent of DOH.
- **13. ATTORNEYS' FEES** In the event of litigation or other action brought to enforce this Agreement, each party agrees to bear its own attorney's fees and costs.
- **14. CHANGE IN STATUS** FHCRC shall notify DOH of any substantive change in the legal status, organizational structure, or fiscal reporting responsibility of FHCRC. FHCRC shall provide notice as soon as practicable, but no later than thirty days after such change takes effect.
- 15. COMMUNICATIONS FHCRC may notify other persons or entities that FHCRC has entered into this Agreement, provided the communication uses terminology approved by DOH and it also clearly communicates FHCRC's independent capacity in accordance with Paragraph 24 of these Terms and Conditions. FHCRC shall not imply it is speaking on behalf of the DOH and will identify itself solely as

a contractor when communicating with third persons in connection with this contract. FHCRC shall not use the DOH or State of Washington logo in communications without express authorization from DOH. FHCRC shall submit to DOH all advertising and publicity matters ("Publicity") relating to this Agreement if, in DOH's judgment, the Publicity mentions, infers, or implies DOH's name. FHCRC shall not publish or use such Publicity without the prior written consent of DOH.

16. CONFIDENTIALITY/ USE AND SECURITY OF PERSONAL INFORMATION

- 16.1. "Confidential Information" means the individually identifiable patient records collected by FHCRC while conducting this SOW regardless of whether FHCRC receives the records from a health care provider, a health care facility, or WSCR.
- 16.2. This Paragraph 16 shall be construed to provide maximum protection to confidential information.
- 16.3. The obligations set forth in this Paragraph 16 shall survive completion, cancellation, expiration, or termination of this Agreement.
- 16.4. FHCRC shall strictly limit use of Confidential Information to the uses specified by the Agreement. More specifically, FHCRC agrees to:
 - 16.4.1. Not link Confidential Information with any other information, unless otherwise authorized under this Agreement.
 - 16.4.2. Not use Confidential Information to identify or contact individuals, except as authorized under this Agreement.

16.5. FHCRC shall:

- 16.5.1. Limit access and use of the Confidential Information in order that the fewest number of people see only the smallest amount of data for the least amount of time necessary to complete required work.
- 16.5.2. Assure that all people with access to the information understand their responsibilities regarding it.
- 16.5.3. Assure that every person (e.g., employee or agent) with access to the information signs and dates a confidentiality agreement that is approved by the DOH.
- 16.5.4. Retain a copy of the signed and dated form as long as required in Paragraph 32, Records, Documents, and Record Retention
- 16.6. FHCRC shall not disclose in any manner all or part of the Confidential Information except as the law requires, this Agreement permits, or with specific prior written permission by the Secretary of the Department of Health.
- 16.7. DOH reserves the right to monitor, or investigate the use of Confidential Information collected, used or acquired by FHCRC through this Agreement as provided in Paragraph 34 of this Agreement.
- 16.8. FHCRC shall assure that its security practices and safeguards meet or exceed the Washington State Office of the Chief Information Officer (OCIO) IT Security Standards:

 http://ofm.wa.gov/ocio/policies/documents/141.10.pdf. Under this Agreement, compliance with OCIO IT Standards means:
 - 16.8.1. Compliance with Federal Information Security Acts (FISMA) security standards and guidelines for Medium impact systems, http://csrc.nist.gov/groups/SMA/fisma/compliance.html, and
 - 16.8.2. Compliance with "Data Security Requirements for Confidential Data" attached hereto and incorporated herein as Appendix B.

- 16.9. FHCRC shall take all steps necessary to prevent unauthorized access, use or modification of the Confidential Information in any form.
- 16.10. FHCRC, through its Information Security Office, shall conduct internal risk assessments of the CSS security practices and safeguards at least once every three years to confirm compliance with the security requirements of this Agreement. FHCRC shall provide the results of the internal risk assessments to the DOH IT Security Officer upon request. FHCRC shall notify the DOH IT Security Officer at 360-236-4432 of any suspected or actual security breach within two (2) business days of discovery.

17. CONFLICT OF INTEREST

- 17.1. If DOH determines a violation of Chapter 42.52 RCW, the Ethics in Public Service Act, or any similar statute, concerning this Agreement and involving FHCRC, DOH may terminate this Agreement by written notice to FHCRC. FHCRC may ask for review of the determination as provided in Paragraph 20 of these Terms and Conditions concerning disputes. DOH's decision to terminate is in DOH's sole discretion and apart from any determination by the Executive Ethics Board or other tribunal.
- 17.2. If DOH terminates the Agreement as provided by this clause, DOH is entitled to pursue the same remedies against FHCRC as DOH could pursue for breach of contract. The rights and remedies of DOH provided for in this section shall not be exclusive are in addition to any other rights and remedies provided by law.
 - **18. COVENANT AGAINST CONTINGENT FEES** FHCRC warrants that no person or selling agent has been employed or retained to solicit or secure this Agreement for a commission, percentage, brokerage or contingent fee (collectively, "contingent fee"). This clause does not apply to bona fide employees or bona fide established agents who FHCRC employs for the purpose of securing business. If FHCRC has breached this Paragraph 18, DOH may (1) annul this Agreement without liability, (2) deduct the amount of the contingent fee from the Agreement amount in Paragraph 3 of these Terms and Conditions, or (3) recover the amount of the contingent fee by other means.
 - **19. DEBARMENT** FHCRC certifies that FHCRC is not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded in any Federal department or agency from participating in transactions. FHCRC agrees to include the above requirement in all subcontracts into which it enters to complete this Agreement.

20. DISPUTES

- 20.1. The parties shall use their best, good faith efforts to cooperatively resolve disputes and problems that arise under this Agreement. Both parties will continue without delay to carry out their respective responsibilities under this Agreement while attempting to resolve a dispute.
- 20.2. If DOH and FHCRC cannot resolve a dispute at the project management level, either party may submit a request for a dispute resolution to the DOH Contracts Unit which shall oversee the following dispute resolution process: DOH shall appoint a representative to a dispute panel; FHCRC shall appoint a representative to the dispute panel; DOH's and FHCRC's representatives shall mutually agree on a third person to chair the dispute panel. The dispute panel shall thereafter decide the dispute with the majority prevailing.
- 20.3. This dispute resolution process constitutes the sole administrative remedy available under this Agreement and shall precede any action in a judicial and quasi-judicial tribunal, unless the parties mutually agree otherwise.
- 20.4. A party's request for a dispute resolution must:
 - be in writing,
 - state the disputed issues,

- state the relative positions of the parties,
- state FHCRC's name, address, and the number of this Agreement,
- be mailed to ATTN: Contracts Manager, DOH Contracts Unit, PO Box 47905, Olympia, WA 98504-7905 within thirty (30) calendar days after the party could reasonably be expected to have knowledge of the issue which he/she now disputes.
- 21. **EFFECTIVE DATE** Unless otherwise specified under period of performance, the effective date of this Agreement and subsequent amendments, if any, is the date of execution. The date of execution is the last date of signature of the parties. No billable activity may take place prior to the date of execution. FHCRC assumes all liability for any expenses incurred prior to the date of execution or in the event the agreement/amendment is not executed.
- **22. GOVERNING LAW -** This Agreement is governed by the laws of the state of Washington and applicable federal laws and regulations. The venue of any legal action or suit concerning this Agreement shall be the Thurston County Superior Court.

23. INDEMNIFICATION

- 23.1. To the fullest extent permitted by law, FHCRC shall indemnify, defend, and hold harmless the state of Washington, DOH, and all officials, agents and employees of the State, from and against all claims for injuries and death arising out of or resulting from the performance of the Agreement. FHCRC's obligation to indemnify, defend and hold harmless includes any claim by FHCRC's agents, employees, representatives, or any subcontractor or its employees.
- 23.2. FHCRC expressly agrees to indemnify, defend, and hold harmless the State for any claim arising out of or incident to FHCRC's or any subcontractor's performance or failure to perform the Agreement. FHCRC's obligation to indemnify, defend, and hold harmless the State shall not be eliminated or reduced by any actual or alleged concurrent negligence of State or its agents, agencies, employees and officials.
- 23.3. FHCRC waives its immunity under Title 51 RCW to the extent it is required to indemnify, defend and hold harmless State and its agencies, officials, agents or employees.
 - **24. INDEPENDENT CAPACITY OF THE CONTRACTOR** This Agreement creates an independent contractor relationship. FHCRC and FHCRC's employees or agents are not employees or agents of DOH and they shall not make any claim of right, privilege or benefit which would accrue to such employee under law. FHCRC shall not claim to be an officer, or employee of DOH or of the Washington State.
 - 25. INDUSTRIAL INSURANCE COVERAGE —FHCRC shall comply with the provisions of Title 51 RCW, Industrial Insurance. Prior to performing work under this Agreement, FHCRC shall provide or purchase industrial insurance coverage for FHCRC's employees, as may be required of an "employer" as defined in Title 51 RCW, and shall maintain full compliance with Title 51RCW during the course of this Agreement. If FHCRC fails to provide industrial insurance coverage or fails to pay premiums or penalties on behalf of its employees as may be required by law, DOH may collect from FHCRC the full amount payable to the Industrial Insurance accident fund. DOH may deduct the amount owed by FHCRC to the accident fund from the amount payable to FHCRC by DOH under this Agreement, and transmit the deducted amount to the Department of Labor and Industries, Division of Insurance Services. This provision does not waive any of the Department of Labor and Industries rights to collect from FHCRC. Industrial insurance coverage through the Department of Labor & Industries is optional for sole proprietors, partners, corporate officers and others, per RCW 51.12.020.

26. INSURANCE

26.1. FHCRC shall provide and maintain insurance coverage as set forth in this Paragraph 26 in full force and effect during the term of this Agreement. The intent is to protect the State from any claims, suits,

- actions, costs, damages or expenses arising from any negligent or intentional act or omission of FHCRC or subcontractor, or agents of either, while performing under this Agreement.
- 26.2. The insurance must be issued by an insurance company/ies authorized to do business in the state of Washington, and shall name the state of Washington, its agents and employees as additional insureds under the insurance policy/ies. All policies shall be primary to any other valid and collectable insurance. FHCRC shall instruct the insurers to give DOH 30 days advance notice of any insurance cancellation.
- 26.3. Upon request, FHCRC shall submit to DOH, a current certificate of insurance showing the coverage and limits required, as follows:
 - <u>Commercial General Liability Insurance Policy</u> Provide a commercial general liability insurance
 policy, including contractual liability, in adequate quantity to protect against legal liability arising out
 of contract activity but no less than \$1,000,000 per occurrence. Additionally, FHCRC is responsible
 for ensuring that any subcontractors provide adequate insurance coverage for the activities arising out
 of subcontracts.
 - <u>Automobile Liability</u>. Automobile liability insurance is required if services delivered pursuant to this
 Agreement involve the use of vehicles, either owned or not owned by FHCRC. The minimum limit
 for automobile liability is: \$1,000,000 per occurrence, using a combined single limit for bodily injury
 and property damage
 - **27. LICENSING, ACCREDITATION AND REGISTRATION -** FHCRC shall comply with all applicable local, state, and federal licensing, accreditation and registration requirements or standards, necessary for the performance of this Agreement.
 - 28. LIMITATION OF AUTHORITY/APPROVAL BY CONTRACTING OFFICER: This Agreement is not binding until signed by the DOH Contracting Officer. Only the Contracting Officer has the authority to modify, amend, or waive any provision of this Agreement. No modification, amendment, or waiver of any provision of this Agreement is effective or binding unless in writing and signed by the Contracting Officer. The DOH Contracting Officer may delegate the authority under this Agreement to another, but such delegation is not effective unless in writing before the action.
 - **29. NONDISCRIMINATION** -- During the performance of this Agreement, FHCRC shall comply with all federal and state nondiscrimination laws, regulations and policies. If FHCRC fails or refuses to comply with any nondiscrimination law, regulation, or policy, DOH may rescind, cancel or terminate this Agreement, in whole or in part, and declare FHCRC ineligible for further contracts with DOH. DOH shall give FHCRC reasonable time in to cure the noncompliance before taking action. The Parties shall seek to resolve any dispute in accordance with the disputes procedure in Paragraph 20 of these Terms and Conditions.
 - **30. NO THIRD PARTY BENEFICIARIES:** DOH and FHCRC are the only parties to this Agreement and are the only parties entitled to enforce its terms. Nothing in this Agreement gives or provides any benefit or right, whether directly, indirectly, or otherwise.
 - **OVERPAYMENTS AND ASSERTION OF LIEN** If DOH makes overpayments or erroneous payments to FHCRC under this Agreement, DOH may secure repayment, including interest, if any, by (1) filing a lien against FHCRC's real property; (2) requiring FHCRC to post a bond, assignment or deposit, or some other form of security acceptable to DOH; (3) or taking both the steps described in (1) and (2).
 - 32. RECORDS, DOCUMENTS, AND RECORD RETENTION
- 32.1 FHCRC shall maintain books, records, documents, data and other evidence relating to this contract and performance of the services described herein, including but not limited to accounting procedures and practices which sufficiently and properly reflect all direct and indirect costs of any nature expended in the performance of this

contract. FHCRC shall retain such records for a period of six (6) years following the date of final payment. At no additional cost, these records, including materials generated under the contract, shall be subject at all reasonable times to inspection, review or audit by DOH, personnel duly authorized by DOH, the office of the state auditor, and federal and state officials so authorized by law, regulation or agreement.

32.2 If any litigation, claim or audit is started before the expiration of the six (6) year period, the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved.

- **33. REGISTRATION WITH DEPARTMENT OF REVENUE -** FHCRC shall register with the Washington State Department of Revenue, if applicable, and be responsible for payment of all taxes due on payments made under this Agreement.
- **34. RIGHT OF INSPECTION** Upon advance written notice where permissible under applicable law, FHCRC shall provide reasonable access to its facilities to DOH, or any of its officers, or to any other authorized agent or official of the state of Washington or the federal government, at mutually agreeable and reasonable times, in order to monitor and evaluate performance, compliance, and/or quality assurance under this Agreement.
- **RIGHTS IN DATA** Use and rights in the data collected under this contract are subject to RCW 70.54.230-.270 and all applicable law.
- **36. SAVINGS** If funding from state, federal, or other sources is withdrawn, reduced, or limited in any way after the effective date of this contract and prior to normal completion, DOH may, in whole or in part, suspend or terminate the contract under the *Termination or Suspension for Convenience* clause, without the ten (10) day notice requirement, subject to renegotiation at DOH's discretion under those new funding limitations and conditions.
- **SEVERABILITY** If any provision of this Agreement or any provision of any incorporated document shall be held invalid, such invalidity shall not affect the other provisions which can be given effect without the invalid provision, and to this end the provisions of this agreement are declared to be severable.

38. SUBCONTRACTING

- 38.1. FHCRC and its subcontractors, if any, shall not enter into subcontracts for any of the work under this Agreement without DOH's prior written approval. The existence of the subcontract shall not operate to release or reduce the liability of FHCRC to DOH for any breach in the performance of FHCRC's duties. This clause does not apply to contracts of employment between FHCRC and personnel assigned to work under this Agreement or to subcontractors that FHCRC may retain to carry out its obligations as an NCI/SEER contractor.
- 38.2. FHCRC shall ensure that all terms, conditions, assurances and certifications set forth in this Agreement are carried forward to any subcontracts, including, but not limited to, the requirements for confidentiality in Paragraph 16 of these Terms and Conditions.
- 38.3. If, at any time during the progress of the work, DOH determines in its sole judgment that any subcontractor is incompetent or undesirable, DOH shall notify FHCRC, and FHCRC shall take immediate steps to terminate the subcontractor's involvement in the work.
- 38.4. The rejection or approval by DOH of any subcontractor or the termination of a subcontractor shall not relieve FHCRC of any of its responsibilities under the Agreement, nor be the basis for additional charges to DOH.
- 38.5. DOH has no contractual obligations to any subcontractor or vendor under contract to FHCRC. FHCRC is fully responsible for all contractual obligations, financial or otherwise, to their subcontractors.

- **39. SURVIVABILITY** The terms and conditions contained in this Agreement which by their sense and context, are intended to survive the completion, cancellation, termination, or expiration of the Agreement shall survive.
- **40. TAXES** All payments accrued on account of payroll taxes, unemployment contributions, any other taxes, insurance or other expenses for FHCRC or its staff shall be the sole responsibility of FHCRC.
- 41. TERMINATION OR SUSPENSION FOR CONVENIENCE Except as otherwise provided in this Agreement, the Contracting Officer may, by ten (10) calendar days written notice, beginning on the second day after the mailing, suspend or terminate this Agreement in whole or in part when it is in the best interests of DOH. If this Agreement is so suspended or terminated, DOH shall be liable only for payment in accordance with the terms of this Agreement for services rendered prior to the effective date of suspension or termination. If DOH elects to suspend the Contract, in whole or in part, FHCRC shall stop work to the extent of the suspension upon receipt of DOH's written notice of suspension. During suspension, each Party will reasonably notify the other of any conditions that may affect resumption of performance. Upon DOH's written notice to resume performance, FHCRC shall resume work unless FHCRC provides notice to DOH that FHCRC cannot resume performance. If FHCRC cannot resume performance, the Contract will be deemed terminated upon the date the Contractor received written notice to suspend performance.

42. TERMINATION FOR DEFAULT

- 42.1. If DOH determines FHCRC has failed to comply with the conditions of this Agreement in a timely manner, DOH has the right to suspend or terminate this Agreement. Further, DOH may terminate this Agreement for default, in whole or in part, if DOH has a reasonable basis to believe that FHCRC has:
 - Failed to meet or maintain any requirement for contracting with DOH;
 - Failed to ensure the health or safety of any client for whom services are being provided under this Agreement;
 - Failed to perform under, or otherwise breached, any term or condition of this Agreement; and/or
 - Violated any applicable law or regulation.
- 42.2. Before suspending or terminating the Agreement, DOH shall notify FHCRC in writing of the need to take corrective action. If corrective action is not taken within fourteen (14) days, DOH may terminate or suspend the Agreement. If Agreement is terminated or suspended, FHCRC shall be liable for damages as authorized by law including, but not limited to, any cost difference between the original contract and the replacement or cover contract and all administrative costs directly related to the replacement contract, e.g., cost of the competitive bidding, mailing, advertising and staff time. DOH reserves the right to suspend all or part of the Agreement, withhold further payments, or prohibit FHCRC from incurring additional obligations of funds during investigation of the alleged compliance breach and pending corrective action by FHCRC or a decision by DOH to terminate the Agreement. A termination shall be deemed to be a "termination for convenience" if it is determined that FHCRC: (1) was not in default; or (2) failure to perform was outside of his or her control, fault or negligence. The rights and remedies of DOH provided in this Agreement are not exclusive and are in addition to any other rights and remedies provided by law.

43. TERMINATION PROCEDURE

- 43.1. Upon termination of this Agreement DOH may require FHCRC to deliver to DOH any property specifically produced or acquired for the performance of such part of this Agreement as has been terminated. The provisions of the "Treatment of Assets" clause shall apply in such property transfer.
- 43.2. DOH shall pay to FHCRC the agreed upon price, if separately stated, for completed work and services accepted by DOH. In addition, DOH shall pay the amount agreed upon by FHCRC and the Contracting Officer for (a) completed work and services for which no separate price is stated, (b) partially completed work and services, (c) other property or services which are accepted by DOH,

- and (d) the protection and preservation of the property. If the termination is for default, the Contracting Officer shall determine the extent of the liability of DOH. FHCRC may ask for review of the determination as provided in Paragraph 20 of these Terms and Conditions concerning disputes.
- 43.3. DOH may withhold from any amounts due FHCRC for such completed work or services such sum as the Contracting Officer determines to be necessary to protect DOH against potential loss or liability.
- 43.4. The rights and remedies of DOH provided in this section shall not be exclusive and are in addition to any other rights and remedies provided by law or under this Agreement.
- 43.5. After receipt of a notice of termination, and except as otherwise directed by the Contracting Officer, FHCRC shall:
 - Stop work under the Agreement on the date and to the extent specified in the notice;
 - Place no further orders or subcontracts for materials, services, facilities except as necessary to complete such portion of the work not terminated;
 - Assign to DOH, to the extent directed by the Contracting Officer, all of the rights, titles, and interest of FHCRC under the orders and subcontracts in which case DOH has the right, at its discretion, to settle or pay any or all claims arising out of the termination of such orders and subcontracts.
 - Settle all outstanding liabilities and all claims arising out of orders or subcontracts, with the approval or ratification of the Contracting Officer to the extent he/she may require, which approval or ratification shall be final for all the purposes of this clause;
 - Transfer title to DOH and deliver, as directed by the Contracting Officer, any property which, if the Agreement had been completed, would have been required to be furnished to DOH;
 - Complete performance of such part of the work not terminated by the Contracting Officer; and,
 - Take such action as may be necessary, or as the Contracting Officer may direct, for the protection and preservation of the property related to this Agreement which is in the possession of FHCRC and in which DOH has or may acquire an interest.
- 44. **WAIVER OF DEFAULT** Waiver of any default or breach shall not be deemed to be a waiver of any subsequent default or breach. Any waiver shall not be construed to be a modification of the terms of this Agreement unless stated to be such in writing and signed by authorized representative of DOH.

IN WITNESS WHEREOF: DOH and FHCRC have signed this Agreement.

FHCRC SIGNATURE	DATE
DOH CONTRACTING OFFICER SIGNATURE	DATE

Approved As to Form Janis Snoey, Assistant Attorney General

Exhibit A

Statement of Work

DOH Contract N21876 - AMENDMENT

Fred Hutchinson Cancer Research Center

1. **DEFINITIONS**:

"Cancer" has the same meaning as "cancer case" defined by WAC 246-102-010(1).

"Case Report" means any report submitted by a Reporting Entity under Chapter 246-102 WAC as directed by DOH.

"Community Laboratory" means a laboratory providing local services only and operates independent of a National/Regional Laboratory.

"CSS Area" means the thirteen counties in western Washington in which FHCRC will collect data under contract with the National Cancer Institute including Clallam, Grays Harbor, Island, Jefferson, King, Kitsap, Mason, Pierce, San Juan, Skagit, Snohomish, Thurston, and Whatcom.

"CSS Area Contract Data" means any information on CSS Area residents in any format that is collected, processed, and stored by FHCRC under this Contract, including, but not limited to Case Reports.

"De-identified" means removal from data of information that reveals or may likely be associated with the identity of cancer case individuals, their relatives, and household members.

"National/Regional Laboratory" means a laboratory providing services on a statewide or multistate basis.

"NCI/SEER" means National Cancer Institute's Surveillance, Epidemiology and End Results Program.

"Non-CSS Area" means the counties in Washington or other States that do not constitute the "CSS Area."

"Non-CSS Area Contract Data" means any information in any format that is collected, processed, and stored by FHCRC on non-CSS area residents under this Contract, including, but not limited to Case Reports

"Reporting Entity" has the same meaning as "reporting entity" defined by WAC 246-102-010(10).

- **2. REPORTING PROTOCOL.** The Parties shall identify cases, abstract and code in conformance with the most current versions of the following, as applicable:
 - The International Classification of Diseases for Oncology;
 - Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual, Collaborative Stage Data Collection System;
 - Multiple Primary and Histology Coding Rules;
 - Facility Oncology Data Registry Standards;
 - SEER Program Code Manual;
 - SEER Rx;
 - North American Association of Central Cancer Registries, Volume II, Data Standards and Data Dictionary.
 - Requirements of the SEER Program

3. CONTRACT DATA USE

- FHCRC may submit to NCI/SEER CSS Area Contract Data collected, processed, and stored under the terms of the contract between the FHCRC and NCI/SEER, provided that all data are de-identified before submission.
- FHCRC may make available to a Reporting Entity any Contract Data originating from that Reporting Entity.
- FHCRC may only use, and provide to third parties, CSS Area Contract Data that are not de-identified for research purposes in a manner consistent with applicable law including Revised Code of Washington Chapter 42.48 and WAC 246.102.070, pursuant to review and approval by the Washington State Institutional Review Board (WSIRB). De-identified Contract Data may be released for the same purposes in accordance with FHCRC's policies.

4. FHCRC RESPONSIBILITIES:

- Any FHCRC communications concerning work under this Contract shall comply with Paragraph 15 of the Terms and Conditions.
- FHCRC may enter into agreements with Reporting Entities located in the CSS Area, if FHCRC determines such agreements are necessary for efficient transfer and management of Contract Data. Such agreements shall conform to all applicable laws protecting the privacy of personal health information (health privacy law) and clearly distinguish data gathered under this Contract from any other data collected under the separate agreement between FHCRC and the Reporting Entity, (i.e., data not collected under the state's authority), if any.
- FHCRC shall receive all Case Reports prepared by Reporting Entities located in the CSS Area, regardless of whether the Case Report is for a Non-CSS Area resident or a CSS Area resident.
- Pathology Reports: FHCRC shall directly receive pathology reports from Community Laboratories serving the CSS Area. FHCRC shall receive pathology reports from Community Laboratories located outside the CSS Area and National/Regional Laboratories from DOH, in accordance with Paragraph 0. ☐ of this Statement of Work. FHCRC shall maintain a list of pathology labs serving reporting facilities in the CSS Area and notify DOH of any changes to this list during the period of this contract.
- FHCRC shall forward all new cancer case information including all treatment and diagnosis information reported to FHCRC for both CSS Area and Non-CSS Area residents to DOH in accordance with deliverable schedule shown in Paragraph 7. FHCRC shall forward all data in a format acceptable to DOH. FHCRC shall forward Non-CSS Area resident reports submitted solely in hard copy, if any, via any suitable manner appropriate to the transportation of confidential health information.
- FHCRC may maintain Non-CSS Area Contract Data related to Non-CSS Area Residents solely for the purpose of efficiency in follow back queries and data management on behalf of Reporting Entities and for no other purpose. FHCRC shall maintain such data in a manner that clearly identifies that the Non-CSS Area Contract Data may not be used for research nor be released to any third party, except as explicitly permitted by the agreements with Reporting Entities. Upon expiration or termination of this Contract, if the Parties agree to extend the term of this Contract or enter into a new agreement for the same purpose, FHCRC shall provide to DOH copies of all agreements with Reporting Entities that provide for FHCRC to release Non CSS Contract Data to third parties or retain such data after the death of the individual to whom the information pertains.
- All transmittals of data shall comply with security of data requirements in Paragraph 16 of the Terms and Conditions. Transmittal between FHCRC and DOH may be accomplished by (1) FHCRC posting a copy

for DOH's download, (2) via Secure File Transfer (SFT) file format, or (3) hard copy, if data is submitted to FHCRC by Reporting Entities solely in hardcopy. FHCRC must begin working with our state's Health Information Exchange, *OneHealthPort*, to submit quarterly deliverables and exchange NAACCR files via the Health Information Exchange by September 30, 2017 and submit a statement of progress. Department of Health is working to transition from using SFT and other methods of data submission to receiving all information through the Health Information Exchange.

- FHCRC is permitted to use mobile devices to collect CSS Area Contract Data, so long as each device protects data as described in Exhibit B.
- Case Consolidation: Upon receiving Case Reports, FHCRC shall merge data from the Case Reports into a
 <u>Consolidated Case Report</u> in conformance with the following:
 - The Consolidated Case Report shall include all data fields and supporting text identified as "required" or "supplemental" by National Program of Cancer Registries (NPCR) and outlined in the current version of the Data Standards and Data Dictionary published by North American Association of Central Cancer Registries (NAACCR).
 - FHCRC shall submit Consolidated Case Reports to DOH at the times specified in Paragraph 7 of this Statement of Work. All Consolidated Case Reports must pass the current NPCR "required" edit metafile electronic edit. FHCRC shall make necessary corrections to any report that fails to pass the electronic edit with the exception of the following:
 - Overrides, which are set in the 60 days prior to the NAACCR Call for Data
 - First and middle name edits regarding embedded spaces
 - Partial social security numbers
 - Supplemental address edit
 - Treatment modality date edits for data prior to diagnosis date 2011.
- Updates and Corrections for CSS Area Residents: FHCRC shall submit an update and/or correct Case Reports for any change to any of the critical fields or field groups listed below at the time specified in Paragraph 7 of this Statement of Work. The files in the must be in appropriate NAACCR format. At its discretion, FHCRC may submit update/correction files at the time of discovery when conducting its quality assurance activities, if such submittal is earlier than specified for the Consolidated Case Report.
 - Date of Birth
 - Date of Diagnosis
 - Primary Site
 - Laterality
 - Histology
 - Behavior
 - Grade
 - Race
 - Ethnicity
 - Collaborative Stage fields
 - Treatment changes or additions
- **Death Clearance** and Vital Status Follow-up for CSS Area Residents: FHCRC shall link identifiable CSS Area Contract Data with the death certificate databases maintained by DOH's Vital Statistics and the

National Death Index maintained by National Center for Health Statistics to update case files for any cancer case deaths among CSS Area Residents. FHCRC shall report such "death clearances" to DOH at time specified in Paragraph 7 of this Statement of Work. FHCRC also shall link CSS Area Contract Data with other databases as it deems necessary in order to meet the requirements for follow-up status specified by NCI/SEER. These linkages may involve transmission of Contract Data on portable media that have been protected as described in Exhibit B.

- Management Reports: FHCRC shall submit updates of a Management Report to DOH at time specified in Paragraph 7 of this Statement of Work. The Management Report shall identify the cumulative total number of CSS Area cases and include a submission/delinquency report for each Reporting Entity. The Management Report shall also include the following lists for the CSS Area.
 - 4..1. <u>Deletions List</u> of cases that, in CSS's opinion, should be deleted from the State Cancer Registry. The list shall include CSS's rationale for the deletion recommendation. DOH is not obligated to take action on CSS's recommendation.
 - 4..2. <u>Limited Release List</u>, which includes (1) any cases for whom FHCRC has received notice that the cases do not want their information released; (2) cases who are diagnosed in a state other than Washington; and (3) s cases for whom the Case Reports were solely obtained from the Veterans Administration facilities. FHCRC shall mark such cases as "VA only."
- Reporting Entity Audits: FHCRC shall annually conduct audits in accordance with NCI/SEER standards to ascertain whether Reporting Entities in the CSS Area are submitting Case Reports in compliance with Chapter 246-102 WAC. FHCRC shall submit an Audit Report including the case finding audit and describing the timeliness of reporting by each Reporting Entity to DOH.
- <u>Facility and Provider Lists</u>: List of all Reporting Entities meeting the description of a "health care facility" under WAC 246-102-010(6), including the Facility Identification Number (FIN) and the identification number assigned by CSS. Also a list of all Reporting Entities meeting the description of a "health care provider" under WAC 246-102-010(7), including the National Provider Identification (NPI) and the identification number assigned by CSS. Provide DOH with updates to lists as needed.
- Quality Control/Quality Assurance: FHCRC shall maintain a quality control / quality assurance program that conforms to NCI/SEER quality assurance protocols.
- FHCRC shall respond to all requests from Reporting Entities, oral or written, for information or clarification about the state cancer registry or reporting requirements under Chapter 246-102 WAC as needed to efficiently conduct work under this Contract. Such communications must be in accordance with Paragraph 15 of the Terms and Conditions.
- Reporting Compliance and Disputes: FHCRC shall notify DOH within 60 days of a Reporting Entity's failure to timely submit Case Reports. If disputes develop between FHCRC and Reporting Entities in connection with the collection of Contract Data under WAC 246-102, FHCRC shall refer the dispute to DOH.
- FHCRC shall forward to DOH all requests for data made by other state cancer registries. See Paragraph 0.□ of this Statement of Work.
- FHCRC will provide DOH remote access to the CSS solely for the purpose of Contract Data lookups and no other purpose.

5. DOH RESPONSIBILITIES:

- For both CSS Area and Non-CSS Area cases, DOH is responsible for (1) responding to requests for information or clarification about the state cancer registry or reporting requirements under Chapter 246-102 WAC, unless expressly provided otherwise in this Contract; (2) education and training about the state cancer registry; and (3) exchanging data with other state cancer registries.
- DOH may, from time to time, conduct independent case-finding and re-coding audits of Reporting Entities in the CSS Area.
- On an annual basis, DOH shall notify Reporting Entities located in the CSS Area of their duty to report and explain that FHCRC is DOH's contractor for this purpose. The notice will include a reporting schedule, FHCRC contacts, and any necessary technical specifications.
- Within 30 days of receipt of notice from FHCRC that a new Reporting Entity has been identified, or an existing Reporting Entity has failed to timely submit Case Reports, DOH shall directly contact the Reporting Entity, or take other action as necessary, to compel reporting. DOH shall not hold FHCRC accountable for the timeliness of a Reporting Entity after FHCRC notified DOH of the failure to report.
- DOH shall directly forward to FHCRC any cancer case information, including treatment and diagnosis information reported to DOH for the following types of cases: CSS Area residents or individuals of uncertain residency being served by a CSS Area Reporting Entity.
- Pathology Reports: DOH shall actively solicit and monitor the delivery of monthly pathology reports from Community Laboratories located in the non-CSS Area and National/Regional Laboratories. Except when pathology reports require manual review or technical problems arise, DOH shall forward to CSS within 24 hours of receipt all pathology reports for (1) individuals diagnosed or treated in the CSS Area based on address of the diagnosing or treating facility and (2) CSS area residents.
- DOH shall seek to resolve quickly any conflicts or compliance issues that arise from FHCRC's collection of cancer case information under Chapter 246-102 WAC.

6. JOINT RESPONSIBILITIES

- The Parties shall **meet in person at least once a year** to develop strategies for performance of respective duties. WSCR shall initiate the scheduling of such meetings, which shall be at a time and place convenient to both Parties.
- The Parties shall **conference monthly by telephone** or other electronic means to coordinate, communicate, and solve on-going problems. WSCR shall initiate the scheduling of such meetings, which shall be at a time convenient to both Parties.
- Synchronization of Registries.
 - 6..1. Both Parties shall cooperate to determine where CSS and WSCR operations and procedures are the same or different as a result of the Parties' respective obligations to NCI or CDC. The purpose of this comparison is to identify the unique services that FHCRC is providing to DOH.
 - 6..2. In January of each year, DOH shall provide to the FHCRC, and FHCRC shall complete and submit to DOH, the NPCR Template for Documenting Hospital, Path Lab, and Physician Reporting Progress to document changes in the electronic reporting status of facilities and providers in the CSS Area.
- The Parties shall work together to define and implement processes by which HIE data are received and managed so that the Parties' respective responsibilities and workflows continue without diminishing pre-HIE levels of data quality and timeliness. DOH shall provide FHCRC with data record descriptions and data dictionaries no later than 6 months prior to the start of data transfers.
- The Parties will collaborate to develop procedures for (1) coordinating changes in reporting source responsibilities prior to implementation of such changes and (2) for FHCRC to provide DOH with case notification administrative support.

7. SCHEDULE FOR DELIVERABLES AND PAYMENT The following schedule shall be used for reporting and payment under this contract. The total payment amount is not to exceed the amount specified in Paragraph 3 of the Terms and Conditions.

Date Due	Deliverables Due	Payment Amount
December 31, 2016	Consolidated Case Reports – New Cases (through diagnosis date 5/31/2016 Management Report	\$30,000
January 31,2017	NPCR Electronic Reporting Template	
March 31, 2017	Consolidated Case Reports – New Cases (through diagnosis date 8/31/2016 Management Report	\$30,000
June 30, 2017	Consolidated Case Reports – New Cases (through diagnosis date 10/31/2016 Management Report	
July 31, 2017	Consolidated Case Reports – New Cases (through diagnosis date 12/31/2016	
August 31, 2017	Updates and Corrections Death Clearances	\$5,000
September 30, 2017	Consolidated Case Reports – New Cases (through diagnosis date 2/28/2017 Management Report Audit Report	\$30,000
AS NEEDED	Updates to Pathology Laboratories List Updates to Facility and Provider lists	

Exhibit B

Data Security Requirements for Confidential Data

DOH Contract N21876

Fred Hutchinson Cancer Research Center

DOH classified the data acquired under the terms of this Contract as "Restricted (Category 4)"

The FHCRC agrees to store data on one or more of the following media and protect the data as described:

- A. Hard disk drives
- 1. Data stored on local workstation hard disks: The data must be encrypted as described under F. Data Storage on portable devices or media.
- Access to the data will be restricted to authorized users by requiring logon to the local workstation using a
 unique user ID and Complex Password or other authentication mechanisms which provide equal or greater
 security, such as biometrics or smart cards. Accounts must lock after 5 unsuccessful access attempts and
 require administrator reset

Complex Passwords are:

- At least 8 characters in length
- Contain at least three of the following character classes: uppercase letters, lowercase letters, numerals, special characters.
- Do not contain the user's name, user ID or any form of their full name
- Do not consist of a single complete dictionary word, but can include a passphrase
- Are changed at least every 120 days.
- B. Network server disks.

Data stored on hard disks mounted on network servers and made available through shared folders:

- 1. Access to the data will be restricted to authorized users through the use of access control lists which will grant access only after the authorized user has authenticated to the network. Authentication must occur using a unique user ID and Complex Password or other authentication mechanisms which provide equal or greater security, such as biometrics or smart cards. Accounts must lock after 5 unsuccessful access attempts, and require administrator reset.
- Data on disks mounted on such servers must be located in a secured computer area, which is accessible
 only to authorized personnel with access controlled through use of a key, card key, combination lock, or
 comparable mechanism.
- 3. If the servers are not located in a secured computer area or if the data are classified as Confidential or Restricted Confidential, it must be encrypted as described under F. data storage on portable devices or media.
- C. Optical discs (CDs or DVDs) in local workstation optical disc drives
 - Data provided on optical discs must be encrypted as described under F. data storage on portable devices or media. When not in use for the purpose of this agreement, such discs must be locked in a drawer, cabinet or other physically secured container to which only authorized users have the key, combination or mechanism required to access the contents of the container.
- D. Optical discs (CDs or DVDs) in drives or jukeboxes attached to servers

Data provided on optical discs must be encrypted as described under Paragraph F, data storage on portable devices or media.

- 1. Access to data on these discs will be restricted to authorized users through the use of access control lists which will grant access only after the authorized user has authenticated to the network.
- 2. Authentication must occur using a unique user ID and Complex Password or other authentication mechanisms which provide equal or greater security, such as biometrics or smart cards. Accounts must lock after 5 unsuccessful access attempts and require administrator reset.
- Data on discs attached to such servers must be located in an area which is accessible only to authorized personnel, with access controlled through use of a key, card key, combination lock, or comparable mechanism.
- E. Access via remote terminal/workstation over the State Governmental Network (SGN) or the Internet
- 1. When data are transferred between DOH and the FHCRC, access to the data will be controlled by DOH, who will issue authentication credentials. FHCRC will notify the DOH immediately whenever:
 - An authorized person in possession of such credentials is terminated or otherwise leaves the employ of the FHCRC
 - Whenever a person's duties change such that the person no longer requires access to perform work for this agreement.
- 2. The data shall not be transferred or accessed over the Internet in any other manner, except as follows:
 - To make contract data originating from a Reporting Entity, in whole or part, available to that Reporting Entity,
 - To provide authorized FHCRC staff access to the database whether it is physically located at the FHCRC, or other facility designated by SEER so long as such a facility is held accountable by FHCRC through contract to comply with all of the privacy and security terms of this contract.
- 3. When the data are accessed as permitted above, secure encryption protocols and multi-factor authentication mechanisms such as; hardware or software tokens, smart cards, digital certificates and biometrics, must be used. During transmission the data must be encrypted using a key length of at least 128 bits. Industry standard mechanisms and algorithms, such as those validated by the National Institute of Standards and Technology (NIST) are required.
- F. Data storage on portable devices or media
- 1. Portable devices include, but are not limited to; Smart Phones, tablets, and ultra-mobile PCs, flash memory devices (e.g. USB flash drives, personal media players), portable hard disks, and laptop/notebook computers.
- 2. Portable media includes, but is not limited to; optical media (e.g. CDs, DVDs), magnetic media (e.g. floppy disks, tape, Zip or Jaz disks), or flash media (e.g. CompactFlash, SD, MMC).
- 3. The data shall not be stored by the FHCRC on portable devices or media. The data shall not be stored by the Information Recipient on portable devices or media unless specifically authorized within the terms of this Agreement. If so authorized, the data shall be given the following protections:
 - Use industry standard encryption mechanisms validated by the National Institute of Standards and Technologies (NIST).
 - Encrypt the data with a key length of at least 128 bits
 - Control access to devices with a Complex Password or stronger authentication method such as a
 physical token or biometrics. Devices must be rendered unusable after 10 unsuccessful access
 attempts.

- Manually lock devices whenever they are left unattended and set devices to lock automatically after a period of inactivity. The maximum period of inactivity is 5 minutes.
- Physically protect the portable device(s) and/or media by
- Keeping them in locked storage when not in use
- Using check-in/check-out procedures when they are shared, and
- Taking frequent inventories
- 4. When being transported outside of a secure area, portable devices and media with data provided under this agreement must be under the physical control of Information Recipient staff with authorization to access the data.

G. Backup Media

Data may be backed up as part of FHCRC's normal backup process provided that it is encrypted and the process includes secure storage and transport.

H. Paper documents

Any paper records must be protected by storing the records in a secure area which is only accessible to authorized personnel. When not in use, such records must be stored in a locked container, such as a file cabinet, locking drawer, or safe, to which only authorized persons have access.

- I. Data Segregation
- 1. Data provided under this agreement must be segregated or otherwise distinguishable from all other data. This is to ensure that when no longer needed by the FHCRC, all of the data can be identified for return or destruction. It also aids in determining whether the data has or may have been compromised in the event of a security breach.
- 2. When it is not feasible or practical to segregate the data from other data then all data, which it is commingled with the data provided under this agreement, must be protected as described in this exhibit

J. Data Disposition

If data destruction is required by the Agreement, the data shall be destroyed using one or more of the following methods:

Data stored on:	Will be destroyed by:	
Server or workstation hard disks	Using a "wipe" utility which will overwrite the data at least three times using either random or single character data, or	
	Degaussing sufficiently to ensure that the data cannot be reconstructed, or	
	Physically destroying the disk, or	
	Delete the data and physically and logically secure data storage systems that continue to be used for the storage of confidential data to prevent any future access to stored information. One or more of the preceding methods must be performed before transfer or surplus of the systems or media containing the data.	

Paper documents with confidential data	On-site shredding, pulping, or incineration, or Recycling through a contracted firm provided the contract with the recycler assures that the confidentiality of data will be protected.
Paper documents containing confidential information requiring special handling (e.g. protected health information)	On-site shredding, pulping, or incineration
Optical discs (e.g. CDs or DVDs)	Incineration, shredding, or completely defacing the readable surface with a course abrasive
Magnetic tape	Degaussing, incinerating or crosscut shredding
Removable media (e.g. floppies, USB flash drives, portable hard disks, Zip or similar disks)	Using a "wipe" utility which will overwrite the data at least three (3) times using either random or single character data Physically destroying the disk Degaussing magnetic media sufficiently to ensure that the data cannot be reconstructed

K. Notification of Compromise or Potential Compromise

The compromise or potential compromise of the data must be reported to the DOH IT Security Officer within two (2) business days of discovery.